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### Remarks

This paper and the following remarks are fully responsive to the Office Action mailed October 29, 2004.

The previously indicated allowability of claims 1-10, 12-15, 17-22, and 24 has been withdrawn. Claims 1-6, 10-13, 16-19, 23, and 24 have been rejected. Claims 7-9, 14, 15, and 20-22 are objected to.

None of the claims have been amended or cancelled and no claims have been added in this paper. After entry of this paper, claims 1-24 are pending.

### **Claim Rejections – 35 USC § 103**

The Examiner has rejected claims 1-6, 10, 13, and 18-19 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,328,077 to Lou ("the '077 patent").

The Examiner states that the '077 patent reports a method of treating urinary stress incontinence by inserting a bone anchor into the wall of the pubic bone. The Examiner is of the opinion that it is well known in the art to provide a suture/sling in order to support the bladder neck and urethra in a urinary stress incontinence procedure and that it would therefore have been obvious to one of skill in the art to utilize a suture/sling in the '077 patent procedure. The Examiner further states that with respect to claims directed to sensory feedback, such feedback is inherent when applying fasteners with hand held devices. The Examiner is also of the opinion that one would feel the change in force in the handle, trigger, or elsewhere when the mechanical action is completed or the fastener has been dislodged.

The Applicant respectfully traverses the rejection.

In contrast to the claimed invention, the '077 patent reports a technique to treat female urinary incontinence that includes permanently stapling the pelvic floor to the pubic bone to raise the urethra and increase the posterior angle of the pelvic floor relative to the bladder. Col. 4, lines 17-20 and Col. 9, lines 27-32. The '077 patent does not report the use of, nor does it contain any suggestion that it would be further necessary to provide, a suture/sling in order to support the bladder neck and urethra. In fact, the '077 patent reports

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that the stapling technique by itself treats female urinary incontinence and even distinguishes the stapling technique from known, invasive, surgical methods that use a suture/sling to suspend the pelvic floor from the pubic bone (after making an incision in the lower abdomen of the patient and approaching the pelvic floor and bladder through the pre-vesical space outside the abdominal cavity), stating that "we are able to do the same surgery with staples...." Col. 1, lines 15-26. Thus, the '077 patent does not teach or suggest using suture/slides with the technique of the '077 patent. Therefore, it would not be obvious to utilize a suture/sling in the '077 patent procedure to obtain the claimed invention.

Accordingly, independent claims 1, 5, 13, and 18 are patentable over the '077 patent and are in condition for allowance. Furthermore, because claims 2-4, 6, 10, and 19 depend from an allowable independent claim, they are also in condition for allowance. Therefore, the Applicant respectfully requests that the Examiner withdraw the rejection and allow claims 1-6, 10, 13, and 18-19.

#### **Claim Rejections – 35 USC § 102(e)**

The Examiner has rejected claims 1-4 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,611,515 to Benderev et al. ("the '515 patent"). The Examiner has also rejected claims 11-13, 16, 17, and 23 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,988,171 to Sohn et al. ("the '171 patent").

The Applicant respectfully traverses these rejections.

Independent claim 1 is directed to a method of treating a female patient for urinary stress incontinence that includes using suture thread and a sling. Thus, the sling of the claimed invention is distinct from the suture thread. The present invention reports that the sling is introduced into the vagina after the suture thread and anchor are inserted and that the suture threads are threaded through holes in the sling, which may be formed of a biocompatible fabric. Paragraphs [0139] and [0156], FIGS 45A-B and 46. The '515 patent, however, reports only the use of suture thread, not suture thread and a sling. In particular, the '515 patent reports a surgical bladder neck suspension procedure that includes creating a

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suspension having a plurality of lengths of suture thread with a suture thread passer. Col. 5, lines 63-67; Col. 6, lines 1-6. The suture thread passer is advanced and withdrawn multiple times through the patient's tissue, specifically between the pubocervical fascia and the pubic bone, and then the suture thread is tied down to the pubic bone using a bone anchor. Col. 5, lines 63-67; Col. 6, lines 1-6; and Col. 19, lines 8-15. Therefore, independent claim 1 is not anticipated by the '515 patent and is in condition for allowance. Because claims 2-4 depend from an allowable independent claim they are also not anticipated by the '515 patent and are in condition for allowance. Therefore the Applicant respectfully requests that the Examiner withdraw the rejection and allow claims 1-4.

With respect to claims 11-13, 16, 17, and 23, the Examiner states that the '171 patent reports the elements of the claimed invention, including a visual indicator device, and that the visual indicator is not entitled to the benefit of the October 18, 1996 filing date of U.S. Pat. No. 5,972,000 to Beyar et al. ("the '000 patent"), which is before the June 26, 1997 filing date of the '171 patent. The Examiner additionally states that Applicant's previous argument that because the suture thread is secured to the fastener, the suture thread will twist as the fastener is rotated and that cessation of the twisting is an indication that the fastener has been inserted is not persuasive. The Examiner is of the opinion that twisting of the suture thread depends on several factors such as the amount of slack in the suture thread, the number of rotations of the fastener, and the manner in which they are connected. The Examiner believes that the visual indicator of twisting is a portion of the new matter added in a later filed application (now U.S. Patent No. 6,334,446). The Applicant respectfully disagrees.

The Examiner states that twisting of the suture thread depends on the manner in which the suture thread and screw are connected. The '000 patent reports a suture thread secured to a screw such as shown in FIG. 1D. As is evident from this figure, the suture thread is secured to the screw similar to the manner in which a thread is received in the eye of a needle. The suture thread is associated directly with the screw such that both elements will remain at rest when either the screw or the suture thread is at rest, or the elements will

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move or rotate when either the screw or suture thread is moved or rotated, regardless of how many times the screw is rotated or how much slack is in the suture. Col. 8, lines 61-63.

As previously stated, the '000 patent reports that the screw is disconnected once the screw is implanted into the bone surface and that the design of the inserter is such that rotational movement is cancelled upon release. Col. 6, lines 18-19 and 41-44. Because the rotational movement of the suture thread, which protrudes from the patient's body, will cease when the screw stops rotating, the physician will be able to determine when full insertion of the screw into the bone has occurred by visually observing the movement of the suture thread. Thus, the '000 patent does report the visual indicator element recited in claims 11-13, 16, 17, and 23 prior to the filing date of the '171 patent. Accordingly, claims 11-13, 16, 17, and 23 are not anticipated by the '171 patent because the '171 patent was not filed before the '000 patent and are in condition for allowance. The Applicant respectfully requests that the Examiner withdraw the rejection and allow claims 11-13, 16, 17, and 23.

### **Claim Rejections – Double Patenting**

The Examiner has rejected claims 12, 17, and 24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,592,610 to Beyar ("the '610 patent") in view of the '171 patent. The Examiner states that the '610 patent reports all the elements of the claimed invention except for the visual indicator elements. The Examiner also states that the '171 patent reports a similar device and method as the claimed invention including a visual indicator. The Examiner is of the opinion that it would have been obvious to one having ordinary skill in the art to provide the '610 patent with visual indicators as reported by the '171 patent so as to recognize when the fastener has been fully inserted or released from the inserter.

The Applicant respectfully traverses the rejection.

The present application claims priority to the '610 patent, which claims priority to U.S. Patent No. 6,334,446 ("the '446 patent"), which claims priority to the '000 patent filed on October 18, 1996. As previously stated, the '000 patent reports the visual

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indicator element recited in claims 12, 17, and 24 prior to the June 26, 1997 filing date of the '171 patent. Further, the '610 patent does not claim visual indicator elements recited in the claimed invention. The double patenting rejection is therefore improper. Accordingly, claims 12, 17, and 24 are patentable over the claims of the '610 patent in view of the '171 patent and are in condition for allowance. The Applicant respectfully requests that the Examiner withdraw the rejection and allow claims 12, 17, and 24. If the Examiner maintains the double patenting rejection, however, the Applicant will file a terminal disclaimer to advance prosecution of this patent application upon notification that the other claims are allowable.

### Claim Objections

The Examiner has objected to claims 7-9, 14, 15, and 20-22 as being dependent upon a rejected base claim but has stated that the claims would be allowable if rewritten in independent form to include all the elements of the base claim and any intervening claims.

As previously stated, independent claims 5, 13, and 18 are each in condition for allowance. Because claims 7-9, 14, 15, and 20-22 depend from an allowable independent claim, they are also in condition for allowance. Therefore, the Applicant respectfully requests that the Examiner withdraw the objection and allow claims 7-9, 14, 15, and 20-22.

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**Conclusion**

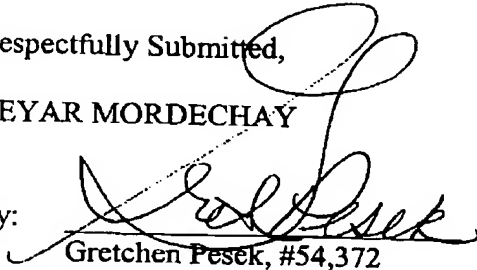
All pending claims are in condition for allowance. A notice to that effect is respectfully requested.

If there are any remaining questions, the Examiner is requested to contact the undersigned at the number listed below.

Respectfully Submitted,

BEYAR MORDECHAY

By:

  
Gretchen Pesek, #54,372  
FAEGRE & BENSON LLP  
2200 Wells Fargo Center  
90 South Seventh Street  
Minneapolis, MN 55402-3901  
612/766-7294

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